CERAPEDICS ANNOUNCES POSITIVE RESULTS FROM IDE CLINICAL TRIAL

Results provide significant support to advance i-FACTOR™ Peptide Enhanced Bone Graft for FDA regulatory review.

WESTMINSTER, Colo. — March 11, 2014 — Cerapedics, Inc., an orthobiologics company focused on developing and commercializing novel peptide enhanced bone graft products based on its proprietary synthetic small peptide (P-15) technology platform, today presented preliminary outcomes data from a FDA Investigational Device Exemption (IDE) clinical trial for i-FACTOR™ Peptide Enhanced Bone Graft in anterior cervical discectomy and fusion (ACDF) procedures. Preliminary analysis of the results indicates that treatment with i-FACTOR met the pre-specified primary end points.

The study was a randomized, controlled, multicenter, prospective trial involving the use of i-FACTOR bone graft vs. autograft for single-level instrumented ACDF procedures inside of a structural allograft ring. Results were presented today by Glen Kashuba, CEO, and Jeff Marx, Ph.D., president and COO of Cerapedics during the Canaccord Genuity Musculoskeletal Conference in New Orleans.

According to preliminary analysis of the trial results, treatment with i-FACTOR showed statistically significant non-inferiority to the autograft control group for fusion rate, neck disability index (NDI) scores, and neurological outcomes. Additionally, i-FACTOR achieved an 89% fusion rate vs. 85% for the autograft control at 12 months; this was also statistically non-inferior with a p value of 0.0003. These results have not yet completed the final phase of quality testing, which could minimally affect final outcome data.

“I want to acknowledge the hard work of all the investigators and their clinical research teams to complete enrollment of this landmark study. We are now working to ensure that we have a high-quality data package from all our clinical sites, and look forward with great anticipation to presenting the encouraging results of this trial to the FDA as quickly as possible,” said Michael Janssen, MD/DO, Spine Education Research Institute, Lakewood, Colorado and principal investigator for the trial.

The data for the IDE have been unblinded and results are being finalized for submission to the FDA. Cerapedics has been submitting the PMA for i-FACTOR in modules, with only the clinical module remaining to be filed. The data are currently being finalized for the PMA clinical module, which is expected to be submitted to the FDA in the second quarter of 2014.

“More than 10,000 patients have now been treated with i-FACTOR around the world. These results provide strong additional confirmation that i-FACTOR could represent a significant advance in ACDF and an alternative to autograft harvesting or expensive growth factor technologies, with important potential advantages for patients, surgeons and surgical practices in the U.S. in the years ahead,” said Mr. Kashuba.

About Cerapedics, Inc.
Cerapedics is an orthobiologics company focused on developing and commercializing its proprietary synthetic small peptide (P-15) technology platform. i-FACTOR Peptide Enhanced Bone Graft is the only biologic bone graft that incorporates a small peptide as an attachment factor to stimulate the natural bone healing process. This novel mechanism of action is designed to support safer and more predictable bone formation at a lower cost compared to commercially available bone growth factors. More information can be found at www.cerapedics.com.

CAUTION: i-FACTOR bone graft is currently not approved for commercial use in any indication in the United States and is limited by U.S. Federal Law to investigational use only.

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